# TROG CANCER RESEARCH

# 2020 ANNUAL RESEARCH Together, we can defeat cancer.

trog.com.au

## ABOUT TROG CANCER RESEARCH

TROG Cancer Research has been improving the way in which radiation therapy is delivered to cancer patients for over 30 years. We are one of the largest clinical cancer trial groups in Australia and New Zealand, specialising in radiation medicine clinical trials, and are renowned internationally.

#### All cancers, one treatment.

Our mission, that TROG will conduct world-class research in radiation medicine that leads the global effort to better control and cure cancer, and improve outcomes for people affected by cancer, provides a clear focus for our organisational efforts.

## **OUR VALUES**

#### COLLABORATION

We work with key stakeholders, organisations and community groups who share our aim of defeating cancer.

#### QUALITY

Our research is guided by rigour, accuracy and innovative methodology.

#### CARE

We provide the utmost care and consideration to trial participants, TROG members, staff and the general community.

#### EQUITY

We strive to improve access and participation in clinical trials.

#### INNOVATION

By being innovative in our research and embracing new technologies, we aim to be a leader in radiation medicine research.



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# **2020 FACTS & FIGURES**

Over three decades, TROG Cancer Research has facilitated hundreds of clinical trials that have helped improve the outcome and quality of life for more than **14,800** cancer patients globally.

Over that time, the prognosis of cancer patients has improved considerably: in the 1980's the cancer survival rate was less than 50%. Today for some cancers the survival rate is as high as 90%.



#### We collaborate internationally, across more than 30 countries.

Our team collaborates with many cancer treatment centres and hospitals: In Australia and New Zealand we have collaborated with over **100** cancer centres and hospitals.

In addition, we have collaborated with over  $\mathbf{80}$  different cancer centres and hospitals internationally.

## **PUBLICATIONS & DISSEMINATION**

210 PEER-REVIEWED MANUSCRIPTS PUBLISHED



2 ABSTRACT PUBLICATIONS

## TROG CANCER RESEARCH PAVE THE WAY FOR A NEW APPROACH TO PROSTATE CANCER TREATMENT

### **TROG 18.01 NINJA TRIAL**

In Australia, prostate cancer is one of the most diagnosed cancers among men. With approximately 3,500 Australian men dying from the disease every year, finding safe and convenient treatments for patients is more important than ever.

TROG Cancer Research, in collaboration with health professionals and research centres across Australia and New Zealand, are working on finding new ways to approach cancer treatment with their TROG 18.01 NINJA trial.

The trial is aimed at assessing new emerging technologies that could be used effectively with existing stereotactic radiation therapy treatment to treat localised prostate cancer.

Co-chair, Associate Professor Jarad Martin, said that with these new emerging technologies prostate cancer patients could be presented with an approach to treatment that is less invasive and more convenient.

"The current regimes in place for prostate cancer patients can require up to 40 daily visits. We understand that this can play a huge mental and physical toll on patients," he said.

"With the NINJA trial we are comparing two emerging and potentially practice-changing radiotherapy schedules that leverage state-of-the-art technology developments to make treatments safer and more convenient for patients."

A/Prof Martin said that whilst there was promising data around the existing approaches in Australia and

internationally, there was no direct comparisons. There was a noticeable gap, which TROG Cancer Research were eager to fill.

"With the NINJA trial we are looking at providing a definitive comparison, using stereotactic monotherapy and virtual brachytherapy boost with new technology to provide more treatment options for prostate cancer patients."

Through the NINJA trial, TROG Cancer Research are introducing highly technological treatments and implanting the use of innovative quality assurance to provide safer treatments for cancer patients.

Ensuring the safety of cancer patients remains a priority across all of TROG's clinical trials and is a common thread across their treatment options.

With NINJA, they hope to improve bio-chemical disease control, treatment planning via automation and planning imaging requirements.

"We are lucky to be in a unique position in Australia where we can properly conduct this trial due to our world leading experience to date and pilot data in all of these areas."

"Successful completion of this trial is likely to result in rapid validation and implementation of two paradigm changes. Firstly, the value of automated treatment planning will be robustly assessed, and if found superior to traditional approaches, become embedded in Australian practice.," A/Prof Martin concluded.

## RESULTS STAND TO CHANGE CLINICAL PRACTICE WORLDWIDE

Group trial bolsters case for stereotactic radiation therapy for tumours that travel to the lungs.

### SAFRON II TRIAL

Randomised, multi-centre Australian phase II trial finds similar safety and efficacy with single- and multiple-fraction treatment for patients with limited oligometastases.

A new study, conducted across 13 medical centres in Australia and New Zealand, strengthens the case for radiation therapy as a treatment for cancer that has begun to spread throughout the body. In the randomised phase II trial, patients with up to three lung metastases who were treated with stereotactic ablative radiotherapy (SABR, also known as stereotactic body radiation therapy, or SBRT) fared equally well whether their radiation was delivered in one or four treatment sessions.

Findings of the SAFRON II trial (NCT01965223) were presented at the American Society for Radiation Oncology (ASTRO) Annual Meeting.

"The future of radiation oncology could be these ultra-short treatments," said lead investigator Shankar Siva, PhD, an associate professor of radiation oncology and head of the SBRT program at the Peter MacCallum Cancer Centre in Melbourne, Australia.

"Our results indicate that SBRT can be a safe and effective treatment for patients whose cancer has spread to their lungs, even when it's delivered in a single session." Up to half of all cancers that start elsewhere in the body spread to the lungs, the second most common site for metastases to occur. These types of tumours are typically treated with drug therapy, but typically the tumours become resistant and come back. In recent years, research has shown that SBRT can help these patients to live longer without their cancer returning.

"For patients with a limited number of metastases, recent studies have shown that there can be longterm survivors with the use of SBRT," said A/Prof Siva. "These studies tend to be smaller institutional series with a wide variety of SBRT regimens, so we designed our trial to test the safety and effectiveness of SBRT in a more robust fashion."

In this phase II TROG Cancer Research trial, 90 patients were randomised into two treatment arms: half received a single fraction of 28Gy. The other half received a biologically equivalent regimen of four fractions of 12Gy each. Each patient had up to three lung metastases from primary tumours in other sites, most commonly colorectal cancer (47%).

A total of 37 patients in each treatment group were eligible for safety analyses one year after treatment. In the cohort who received a single treatment, no participants experienced any serious side effects.

The researchers compared survival rates between the groups a year after treatment and found them nearly identical across both regimens. A/Prof Siva said the team will continue to analyse these secondary endpoints up to three years after treatment, as well as quality of life and costeffectiveness.

If proven safe and effective over the long-term, single-fraction SBRT can be an appealing treatment for patients with oligometastatic cancer to the lungs, said A/Prof Siva.

In addition to clinical benefits, SBRT has practical benefits for patients, such as fewer trips to a clinic, less time off work and lower treatment costs. "The alternative treatments for oligometastatic cancer are ongoing drug therapies with little expectation for long-term control or surgery, which can have difficult side effects. Radiation is non-invasive, and treatment can be delivered in a relatively short time," said A/Prof Siva.

The COVID-19 pandemic has encouraged more significant consideration of shortercourse therapies, as medical institutions look for ways to reduce potential exposure, especially among vulnerable patients with cancer.

"In a pandemic, the idea of a single, non-invasive outpatient treatment that does not require anaesthesia is appealing in the sense of reducing patient time and transmission risk in the clinic," he said. SBRT is typically spread out over up to five treatment sessions. "When we compress a multi-treatment course into a single treatment, there is a potential risk of higher toxicity. Based on our own anecdotal experience, we are quite comfortable using the single treatment approach, but globally, it's used less often," explained A/Prof Siva.

"There also are concerns that a single treatment might not have the same kind of effectiveness as multiple treatments.

Thankfully, in this study, at least a year out, we see similar efficacy, where 93-95% of the tumours were controlled in both arms. Our final analysis will show if this holds for the long-term, but these early results indicate that single-fraction radiation could be carried out equally effectively across multiple institutions."

That the study was conducted across 13 institutions speaks to the general applicability of its findings and the SBRT approach, said A/Prof Siva. He also stressed the importance of incorporating quality assurance into its rollout, however. "The safe delivery of SBRT, particularly in a single session, requires a multi-faceted system of quality assurance, peer review and treatment planning.

You need to be absolutely certain of the accuracy of your treatment delivery, and I think it is very important that treatment teams achieve the same high levels of quality control, to make sure we are achieving the best in cancer care."

Attribution to the American Society for Radiation Oncology (ASTRO) Annual Meeting requested in all coverage. This study was funded by Cancer Australia.

## a message from PRESIDENT & BOARD CHAIR

Dr. Giuseppe Sasso

The past year has been another busy period for TROG Cancer Research with many new initiatives at all levels already showing positive results.

At a Board level, we confirmed Puma Sundaresan and Fiona Hegi-Johnson as elected Directors, each for an additional three-year term. We were thankful for the contribution of Madhavi Chilkuri as RANZCR representative during 2020 and look forward to welcoming Keen Hun Tai into this role in 2021. The Board also formally appointed Bernadette Symth as Company Secretary in August 2020. Bernadette has been assisting with Board governance, compliance, performance review and succession planning, all of which will hold us in good stead going forward.

The Board approved the TROG 2020-2023 Strategic Plan in April 2020 and I was delighted to see the progress made throughout the year in achieving many of the goals and performance measures.

Our mission to be a leader in radiation oncology research has evolved to encompass radiation medicine research while maintaining our fundamental strengths of patient-centred and practicechange, with a new focus on cost efficiency.



Moving forward, TROG Cancer Research is implementing an annual strategic planning meeting of Board members. This will monitor performance against the strategic plan and enable the Board to be responsive to changes in the clinical research environment. In 2020 the Board also conducted a review of the TROG Constitution to ensure alignment with the modern research landscape. Several changes to the constitution are proposed which will be put to a member vote in 2021.

The emergence of the COVID-19 pandemic in early 2020 posed new challenges for the TROG Central Operations Office (TCOO) and the Board. Due to the rapidly changing situation and the need for the Board to manage associated risks, the Board convened and scheduled several virtual meetings during each quarter. With the support of the TROG Finance, Audit and Risk Management (FARM) Committee, the TCOO implemented new processes for financial reporting enabling more detailed and timely reporting to the Board.

A halt on almost all international and (at times) domestic travel during 2020 limited my ability to execute the role of TROG President as I had hoped, given I am New Zealand based. However, we embraced technology to ensure we remained connected, even if it had to be over video conference. There have been efficiencies in travel time and resources. We are looking forward to hosting future face-to-face events as we know these networking opportunities are highly valued by our members.

With all the challenges of 2020, I am so incredibly proud of what TROG Cancer Research achieved throughout the year. Some of the highlights include:

- Pivoting from a face-to-face to a virtual ASM in just over one week.
- Supporting trial investigators and trials site staff during the pandemic via clear and timely communication.
- Continuing with the review of our internal systems and processes, including developing a new TROG website and Trial Management Database (due for launch in 2021).
- A review of the data/repository needs to support future secondary data analysis of TROG trials data. This includes several submissions to seek funding for this purpose.

- Trial activity continuing with three trials reaching accrual, three new clinical trial proposals submitted, and 106 participants recruited.
- Increased engagement with relevant disciplines in the world of radiation medicine (radiology, medical physics, radiation therapy, allied health, and so on).
- New investigator-initiated trials developed collaboratively with other national Cancer Collaborative Trials Groups (CCTGs).

Finally, a huge thank you to all of our members for your hard work, support and involvement in TROG Cancer Research. As a member-based organisation, your input is critical to our success, whether on a working party, a trial management committee, an expert RTQA reviewer, or one of the many other roles voluntarily fulfilled by our members. In addition, I would like to thank all Board members, the central office staff, sponsors and supporters for your commitment during 2020. I look forward to what can be achieved in 2021 and beyond.

## A MESSAGE FROM CHIEF EXECUTIVE OFFICER



Susan Goode

The COVID-19 pandemic in early 2020 posed significant challenges to TROG Cancer Research and influenced our activities over the year in unexpected ways.

In March 2020, we made the difficult decision to cancel our face-to-face Annual Scientific Meeting (ASM) and switch to a live virtual event. Thanks to the hard work of the TROG team, ASM Co-convenors A/Prof Puma Sundaresan and Ms Jo Page, and the team at Encanta Event Management, we managed to pivot to a virtual ASM in less than 10 days - a demonstration of our innovation and problemsolving skills. Although the virtual experience was very different, our members were still able to engage in trial updates. This included discussing new trial concepts and learning from our international keynote speakers.

The pandemic also changed how and where we worked during 2020. The TROG Central Operations staff transitioned to working from home in mid-March and for the remainder of the year. We implemented several new communication platforms (including Zoom and MS Teams) to ensure continued productivity and connectivity whilst working from home. Other adaptations resulting from the COVID 19 pandemic included the implementation of electronic signing for legal agreements and the ability for clinical trial participant consent to occur via telehealth. These innovations are here to stay and will help us to be more productive.

Working from home was not without its challenges, particularly regarding orientation and training for new

staff. In 2020 we welcomed Kassandra Wagenfuehr, Ryan Davey, Sarah Davenport and Bernadette Smyth to the TROG team. During the second half of 2020, we had several staff take parental leave (congratulations to Tamica Humby, Rachael Dykyj, and Olivia Cook on their new arrivals). We subsequently welcomed some new team members to fill these vacancies - Kate Hourigan, Andy Grose and Penny Yates.

In 2020 we continued to work collaboratively with local, state and national organisations, including new collaborative trials with other Australian Cancer Collaborative Trials Groups such as BCT, AGITG, ANZUP, and MASC.

We implemented the first year of activities under the TROG 2020-2023 Strategic Plan, with over 90% of KPIs met or partially met during 2020.

In 2021 we look forward to implementing our strategic plan with a strong focus on a balanced clinical trial portfolio. We're also eager to continue supporting the engagement with our TROG members and our Facility Alliance members.

Overall, I am privileged to lead TROG Cancer Research, and I am incredibly proud of how our staff, investigators, members and clinical trial participating sites worked together during 2020 to ensure another successful year.



## Intelligent Cancer Care

Cancer touches us all in one way or another. That's why every effort put into the fight must tear down the walls separating patient from progress with more intelligent ideas and answers. **Intelligent Cancer Care™** is building shorter paths from research to remission. Bridging the distance between Melbourne and Mozambique. Driving a direct link from high tech to high impact. And resolutely facing today's unique challenges by connecting us all through more intelligent solutions, data, and insights to deliver advanced care—ultimately helping us realise our vision of a world without fear of cancer.

#### We're all connected through Intelligent Cancer Care.

#### Learn more at varian.com/intelligence

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## RADIATION THERAPY QUALITY ASSURANCE 2020 PROJECTS UPDATE

TROG's Radiation Therapy Quality Assurance (RTQA) program provides the framework to monitor radiation therapy protocol compliance and clinical trial data quality.

Advanced techniques and technology in radiation oncology continue to evolve, which in turn requires the TROG RTQA team to remain dynamic and nimble. Inevitably, the RTQA team collaborate on a range of special projects. Some highlights include:

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#### Virtual EPID Standard Phantom Audit (VESPA)

- PI: Prof. Peter Greer

A novel remote method for external dosimetric Treatment Planning System (TPS) - planned auditing of intensity modulated radiotherapy (IMRT) and volumetric modulated arc therapy (VMAT) for clinical trials using an electronic portal imaging device (EPID).

#### Sensitivity assessment system to improve quality in Radiation Oncology treatments (SEAFARER)

#### - PI: A/Prof. Joerg Lehmann

A novel project that sought to identify pilot methods to systematically and remotely test the sensitivity of a centre's Patient Specific Quality Assurance (PSQA) procedures to detect clinically relevant treatment delivery problems. Results of this pilot project have indicated variability in this sensitivity of PSQA. Future project expansion is planned with the potential to offer a novel tool in radiation therapy quality assurance.



#### AusCAT (formerly OzCAT) -Australian Cancer Data Network

- Distributed learning from clinical data
- PI: A/Prof Lois Holloway

The Cancer Data Network project will establish a nationally agreed capability to link regular treatment (clinical practice) data and clinical trial data, for machine learning analysis with international links. The data analysis is performed wherever the data resides, allowing learning across jurisdictions. This will improve data accessibility and provide governance structures to support data users including clinicians, data scientists, governments and policy makers.

The AusCAT team successfully secured funding through the Australian Research and Data Commons (ARDC) Data Platforms round in 2020. An AusCAT node will be established at TROG, improving findability, accessibility, interoperability and reusability of TROG clinical trial data.

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#### Knowledge-based Planning (KBP)

A novel approach to TROG RTQA methods continues to be piloted using Knowledge-Based Planning (KBP) to provide a systematic method for patient-specific qualitative feedback.

TROG trials in the pilot program include: TROG 15.01 SPARK, TROG 15.03 FASTRACK II, TROG 17.03 LARK and TROG 18.01 NINJA.

## TROG SCIENTIFIC COMMITTEE

# A MESSAGE FROM THE TSC CHAIR

Prof. Trevor Leong, TSC Chair

#### Despite the challenges resulting from the COVID-19 pandemic, the TROG Scientific Committee (TSC) enjoyed a busy and productive year.

During early 2020, the clinical trials space was in a state of chaos and confusion. The TSC response to the pandemic was developed in two stages:

1. General communication on COVID-19 and TROG business operations; and

2. Release of specific guidance documents relating to COVID-19 for each TROG trial.

These outline recommendations for:

- recruitment,
- alternative methods for conducting protocol specified visits,
- modifications to existing patient visit requirements,
- early engagement with governing HREC if changes to the protocol were anticipated,
- careful and consistent documentation of protocol deviations.



In spite of the lockdowns and strains on the healthcare system, recruitment to TROG trials did not drop significantly from the previous year.

Some trials, including OUTRUN, NINJA and Local HER-O performed better than anticipated. Specific changes implemented during the pandemic have been beneficial in streamlining the process of clinical trial conduct.

Moving forward, TCOO will continue to adopt reduced on-site visits, central and remote monitoring, telehealth, teletrials and electronic signatures.

The TSC welcomed Dr Christopher Brown as the new discipline representative for statistics. I would like to thank the outgoing committee member Prof Val Gebski for his many years of tireless service to TROG. Val joined the TSC in October 2011.

He is the group statistician for several national collaborative clinical trials groups in addition to TROG, and his extensive knowledge of clinical trial methodology, conduct and analysis has been invaluable.





There are currently Subspecialty Working Parties for Breast, Lung, Head and Neck/Skin and Genitourinary tumour streams. Due to the events of 2020, activation of the Central Nervous System (CNS) Working Party was delayed, but the first meeting will take place soon with Mark Pinkham as the inaugural Chair.

June Corry and David Pryor have stepped down as Chairs of the Head and Neck/Skin and Genitourinary Working Parties, respectively, and I would like to thank them both for their leadership and tremendous efforts over the years.

Charles Lin has been appointed Chair of the Head and Neck/Skin Working Party, while Shankar Siva has been appointed Chair of the Genitourinary Working Party.

In 2020 there were three new trial proposals submitted (CHEST-RT, CHyPPR and I-MAT), two of which were category A, and one was category C. CHEST RT has secured funding, and the trial protocol has been fully developed, due to open in mid-2021. There were also seven category D proposals for secondary analysis of previous TROG trials.

One trial opened to accrual (18.06 FIG), three trials completed accrual (14.02 RAIDER, 16.01 Local HER-O, 12.03 PET LABARADOR), and two trials closed to follow-up (13.01 SAFRON II, 17.06 SC.24). Fourteen manuscripts relating to TROG studies were published in 2020.

In total, 14,821 patients have been recruited to TROG studies, with 106 recruited in 2020.

I would like to acknowledge the enormous efforts of the TSC and subcommittees throughout the year, including the Subspecialty Working Parties, Secondary Data Analysis Committee (SDAC), New Techniques and Technology Committee (NTTC), Independent Data and Safety Monitoring Committee (IDSMC) and the Special Interest Groups.

## A MESSAGE FROM THE FINANCE AUDIT & RISK MANAGEMENT COMMITTEE



Dr. Tim Kuypers

The main focus of the Finance Audit and Risk Management Committee (FARM) this year was to manage the financial performance of TROG Cancer Research throughout the uncertainty of COVID-19.

The FARM, a subcommittee of the Board, met six times during 2020, with our focus for 2021 to continue closely monitoring the impacts of COVID-19, as government subsidies are withdrawn, and make changes where and if necessary.

A strong focus on costs will continue to be important for consistent review throughout this period.

Our objective remains to improve our financial performance with the continued delivery of excellent outcomes for grant funders and improvements in our fee for service financial outcomes.

I wish to thank fellow members of the FARM committee for their diligence and commitment, as well as the CEO and wider team for their hard work during what was a unique and difficult work environment.



## **FINANCE REPORT**

## TROG 2020

#### Despite the challenges of COVID-19, we are pleased to share the strong financial results of 2020.

This was made possible by our hardworking team, and the support of members, sponsors, and the government.

Revenue increased by 23 per cent to \$3,034,709. This figure includes \$626,950 of government support through JobKeeper and cash flow boost schemes. Removing this support, underlying revenue was \$2,407,759, which was down 2.3 per cent on our 2019 results. This is a strong outcome, given reduced clinical trial activity during the height of COVID-19.

Costs increased to \$2,539,881, due to an increase in staff costs. But after removing the JobKeeper top-up payment, which we were required to make, the cost increase was just over 1.2 per cent. Administration costs were down by around 1.5 per cent.

The surplus for 2020 was \$494,828, resulting in our accumulated surplus (reserves for dealing with future challenges) growing to over \$1.5m. This increased surplus is welcomed, given the uncertainty around government COVID-19 support.



**TROG ACCUMULATED SURPLUS 2015 - 2020** 







# **BOARD OF DIRECTORS**

## TROG 2020



Dr. Giuseppe Sasso President

Dr. Giuseppe (Peppe) Sasso is our President, and is immediate past Clinical Director of the Radiation Oncology Department at Auckland City Hospital. He sits on the Auckland District Health Board, and is the past Chairman of the Radiation Oncology Working Group of the New Zealand Ministry of Health, and is an Honorary Academic at the University of Auckland.

He has worked as a Radiation Oncologist in Italy, the UK, Australia, France, Abu Dhabi and New Zealand. He specialises in the treatment of genitourinary and head and neck cancers, with a special interest in stereotactic ablative body radiotherapy (SABR) and the use of MR imaging in radiation therapy.



Prof. Trevor Leong Scientific Committee Chair

Prof. Trevor Leong is a Consultant Radiation Oncologist and is the immediate past Director of Radiation Oncology at Peter MacCallum Cancer Centre in Melbourne.

He is internationally recognised as a leader in the management and research of gastrointestinal cancers, and is actively involved as Trial Chair for numerous TROG Collaborative trials.

Trevor has been involved with our organisation for almost 20 years as a Trial chair, member and Chair of the TROG Scientific Committee and Board Director, as well as being a key contributor to clinical trial radiation therapy quality assurance.



Dr. Fiona Hegi-Johnson Full Member Director

Dr. Fiona Hegi-Johnson is a Radiation Oncologist at the Peter MacCallum Cancer Centre in Melbourne. She is also a Conjoint Senior Lecturer at the University of Newcastle. Clinically, Fiona specialises in the treatment of patients with lung, breast, and head and neck cancer.

She is also Chair of the TROG Lung Subspecialty Working Party and a current member of the TROG Finance Audit and Risk Management Committee.



A/Prof. Puma Sundaresan Full Member Director

A/Prof. Puma Sundaresan is a Senior Staff Specialist in Radiation Oncology at Western Sydney Local Health District (Blacktown and Westmead Hospital), specialising in head and neck, skin, lower gastrointestinal and haematological malignancies.

As a Clinical Associate Professor at the University of Sydney, she is actively involved in teaching medical and allied health students as well as research, which includes supervision of higher degree research students.

Puma is an Associate Editor for JMIRO, the official journal of the RANZCR and is a current member of the TROG Scientific Committee.



Prof. Annette Haworth
Full Member Director

Prof. Annette Haworth specialises in Medical Physics and is the Director of the Institute of Medical Physics at the University of Sydney.

She has more than 20 years of hospital-based clinical experience and has been involved in TROG Cancer Research activities for over 15 years.

During this time, Annette has been a member of the New Techniques and Technologies Committee, the Scientific Committee, the Radiation Therapy Quality Assurance Team, a representative on the Global Harmonisation Group, as well as a member of multiple Trial Management Committees.

Annette's contribution to our organisation was recognised in 2017 with a Life Member Award.



Dr. Madhavi Chilkuri RANZCR Representative

Dr. Madhavi Chilkuri is a radiation oncologist at the Townsville Cancer Centre and Adjunct Senior Lecturer at the James Cook University in Queensland.

She specialises in the management of head and neck, thoracic and upper gastrointestinal malignancies.

Madhavi is Dean of the Faculty of Radiation Oncology, Royal Australian and New Zealand College of Radiologists (RANZCR), also serving on RANZCR's Board of Directors. In addition, Madhavi is a member of the Australia Institute of Company Directors.



Dr. Tim Kuypers Independent Director

Dr. Tim Kuypers is an experienced Non-Executive Director and Senior Executive with significant expertise in highly regulated industries such as health, transport and telecommunications.

Currently, Tim is a Special Advisor for HoustonKemp Economists, the Principal at Walbrook Partners, a rail safety consulting firm, and is the Chairperson of the TROG Finance, Audit and Risk Management Committee.

Tim also sits on the Rail Industry Safety and Standards Board and the Metro Trains Melbourne Board Safety Committee.



Mr. Denis Byron Independent Director

Mr. Denis Byron is a recently retired CEO with very extensive experience in the aged care and primary health sectors.

He is a Certified Practicing Accountant and Australia Institute of Company Directors member.

Denis brings a wealth of knowledge to the TROG Board as an Independent Director, and is a current member of the TROG Finance Audit and Risk Management Committee.



Mr. Rob Ferguson Independent Consumer Representative

Mr. Rob Ferguson is a consumer advocate for cancer patients at St Vincent's Hospital and a Telephone Support Group Counsellor at Cancer Council NSW.

Rob was formerly Chair of Muscular Dystrophy Foundation Australia, President of Muscular Dystrophy NSW, and a Director of Colliers International.

He is a current member of the TROG Finance Audit and Risk Management Committee.



43 international cancer centres
 Centres under construction or announced

# lcons in cancer care

Icon Group is Australia's largest dedicated cancer care provider with a growing reach into New Zealand and Asia. The Group is built on a strong but simple vision – to deliver the best cancer care possible, to as many people as possible, as close to home as possible.

#### Our comprehensive services

State-of-the-art centres across Australia, New Zealand, Singapore, Mainland China and Hong Kong

#### The latest in radiation therapy treatment techniques and technology:

- First in Australia to install a Varian Halcyon System
- First to offer HyperArc treatment cutting-edge precision radiation benefitting secondary brain tumours
- First in southern hemisphere to deliver AI treatment on Varian's Ethos therapy

#### Our dedication to research and clinical trials:

- Largest private provider of oncology clinical trials
- Providing patients with access to new cancer treatments via breakthrough trials and research programs
- Over 25 years' experience in medical oncology and haematology trials
- Delivering unique radiation oncology investigator-initiated trials across a wide-range of tumour streams
- Actively involved in over 130 trials



View our 2020 Annual Research Report To be part of our iconic conversation follow us at:

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# **OUR PEOPLE**

## TROG 2020

## **COLLABORATIVE GROUP SERVICES**

TROG Cancer Research Collaborative Group Services provide oversight for the sponsorship of clinical trials. This may be in conjunction with or independent of TROG specialist Central Trial Coordination and RTQA functions.

Collaborative Group Services enables us to provide specialist support to our members through grant administration, collaborative trial insurance and indemnity, comprehensive legal contracting, financial remuneration, regulatory compliance and reporting.

Additionally, Collaborative Group Services provides central activities to support the conduct of trials, including the facilitation of an Independent Data and Safety Monitoring Committee (IDSMC) to support all of the clinical trials in the portfolio.

## **RESEARCH SERVICES**

#### **DEVELOPMENT AND OPERATIONS**

TROG Cancer Research fosters and promotes the design and conduct of high-quality investigator-initiated cancer collaborative clinical trials involving radiation. The Research Services team provides comprehensive clinical trial development and operations functions.

The Research Services Development team provides comprehensive clinical trial development via the TROG new proposal pathway. This ensures all clinical trials developed are peer-reviewed and robust. They support proposals in development from a new concept or idea and into a complete protocol.

TROG Research Services team supports the following activities:

- Develop new clinical trial concepts
- Develop robust clinical trial protocols
- Provide database development services and advice
- Support applications for research funding
- Ensure expert review of all trial concepts and protocols via the TROG Working Parties and TROG Scientific Committee

The Operations team oversee the management of our clinical trials from startup within the TROG central trial coordinating centre. The Operations team work closely with investigators to coordinate all aspects of the clinical trial activities during the life cycle of a trial until closeout and publication.

TROG Research Services provides comprehensive clinical trial coordination and oversight, including:

- Provide expert central trial coordination
- Data management and oversight
- Support participating sites
- Facilitate patient recruitment
- Monitor patient safety
- Ensure regulatory compliance

- Ensure reporting requirements are met
- Provide administrative support to Trial Chair and Trial Management Committee
- Ensure oversight by TROG Working Parties, TROG Scientific Committee and TROG Publication committee for the trial duration

### **BUSINESS SERVICES**

TROG Cancer Research supports a range of essential business functions, including information technology, events management, financial management, human resource management, governance, regulatory compliance, and communication and marketing services in support of our staff, members and research portfolio.

In August 2020, we welcomed Bernadette Smyth to our Business Services team in the role of Company Secretary and Business Advisor. We continue to review the most efficient mechanisms to fulfil these business functions with the following services outsourced during 2020:



INFORMATION TECHNOLOGY



HUMAN RESOURCES AND WORK HEALTH AND SAFETY



ASM EVENT MANAGEMENT



COMMUNICATIONS AND MARKETING



FINANCIAL AUDIT



### **RADIATION THERAPY QUALITY ASSURANCE**

TROG's Radiation Therapy Quality Assurance (RTQA) program provides the framework to monitor radiation therapy protocol compliance and clinical trial data quality. Our RTQA Program is integral to ensuring data accuracy so that reliable trial results can be published and adopted into clinical practice. RTQA also ensures that safety issues for patients on trial are identified and rectified promptly.

TROG is committed to collaboration with national and international experts and continues to review international standards for credentialing new techniques and technologies in radiation medicine. Technologically advanced software and procedures are continually being incorporated into TROG's RTQA program. In doing this, we ensure our members have access to the best available resources for conducting TROG research. The TROG RTQA team actively supports clinical trial activities through:

- The development of robust risk-adapted radiation therapy planning, delivery and quality assurance guidelines
- Facilitating the development of guidelines, incorporating new techniques / technology into future TROG trials
- Monitoring feedback on protocol compliance and radiation therapy plan quality
- Maximising collaborative efforts to ensure TROG maintains high standards and responds to changing national and international best practice
- Ongoing horizon scanning and forward planning

2020 was a big year for the RTQA team. We collaborated on new studies with other collaborative cancer clinical trials groups such as the Melanoma and Skin Cancer Trials Group on the Immunotherapy Merkel Adjuvant Trial, I-MAT (03.18) via radiation therapy quality assurance services.

Software and infrastructure was also a significant focus. We upgraded to MIM v7, increased our licensing and access capacity, continued work with RapidPlan knowledge-based planning, and implemented ClearCheck software for site feedback.

# **SCIENTIFIC COMMITTEE**

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## **TROG 2020**

#### DIRECT BOARD APPOINTED POSITIONS

POSITION	ΝΑΜΕ
Scientific Committee Chair	Prof. Trevor Leong Peter MacCallum Cancer Centre

#### **APPOINTED POSITIONS**

POSITION	NAME
Radiation Oncology	A/Prof. Puma Sundaresan Westmead Hospital
Radiation Oncology	A/Prof. Sashendra Senthi William Buckland Radiotherapy Centre
Radiation Oncology	Prof. Michael MacManus Peter MacCallum Cancer Centre
Radiation Therapy	Ms. Shivani Kumar Liverpool Hospital
Medical Oncology	Dr. James Lynam Calvary Mater Newcastle
Interventional Oncology	Dr. Jonathon TibballIs Sir Charles Gairdner
Statistics (as of Nov 2020)	Dr. Chris Brown NHMRC Clinical Trial Centre
Statistics (until Oct 2020)	Prof. Val Gebski NHMRC Clinical Trial Centre
Physics	Prof. Paul Keall The University of Sydney
Consumer Representative	Mr. John Stubbs

#### **EX OFFICIO POSITIONS**

POSITION	NAME
Health and Pharmaco-economic technical service	A/Prof. Richard De Abreu Lourenço Centre for Health Economics Research and Evaluation, University of Technology Sydney
QoL technical service	<b>Prof. Madeleine King</b> Sydney Quality of Life Office, University of Sydney
TROG Research Manager	Mrs. Renee Swanson TROG Cancer Research
TROG Radiation Therapy Manager	Ms. Alisha Moore TROG Cancer Research
TSC Secretary	Ms. Rebecca Montgomery TROG Cancer Research

# COMMITTEES

## TROG 2020

### INDEPENDENT DATA AND SAFETY MONITORING COMMITTEE

The Independent Data and Safety Monitoring Committee (IDSMC) ensures that TROG trials fulfil ethical and safety requirements and wherever possible that each trial meets its primary objectives.

The rights, safety and welfare of trial participants are of key consideration in the continual assessment of each TROG trial by the IDSMC. Functioning independently of the TROG Central Operations Office, TROG trials and other TROG Committees, and feeding into the TROG Scientific Committee, the IDSMC meet at sixmonthly intervals to fulfil these important functions.



Prof. Bryan Burmeister Chairperson/Radiation Oncologist

Mrs. Peta Forder Statistician

Prof. Michael Michael Medical Oncologist

A/Prof. Guy Hingston Surgical Oncologist

A/Prof. Paul Nguyen Radiation Oncologist

### **NEW TECHNIQUES AND TECHNOLOGIES COMMITTEE**

The New Techniques and Technologies Committee (NTTC) comprises medical physicists, radiation therapists and radiation oncologists as well as TROG Central Office representatives. The scope of the committee is to provide guidance and where necessary advice on quality assurance requirements for the use of new technology and techniques in TROG trials.

Some significant recent developments in technology and treatment methods, including MRI Linacs and online adaptive treatments, have been recently released and require careful analysis to ensure the continuation of TROG's high-quality trial data and conduct.

Several sub-groups are working on guidelines for specific complex areas, including stereotactic radiosurgery trials, image registration, MRI in radiation therapy, and a sub-group developing a risk assessment approach for required quality assurance for new trial applications. Other pertinent issues have been the standardisation of naming conventions/nomenclature for treatment planning in trials to aid in reporting and comparisons of results and automation of plan quality assurance.

We continue to liaise with several other groups, including the Australian Clinical Dosimetry Service and the Global Harmonisation Group. Several quality assurance projects are underway including the SEAFARER assessment of patient-specific quality assurance for which significant grant funding has been applied. Facility questionnaires are also currently under review. Discussions on TROG's quality assurance infrastructure, including that for secondary analysis, are ongoing.

Prof. Peter Greer		
Chairperson	Mr. Rob McDowall	Dr. Nick Hardcastle
Mr. Michael Bailey	Mr. Kenton Thompson	Mr. Andrew Cousins
Prof. Martin Ebert	Mr. David Willis	Ms. Alisha Moore
Prof. Annette Haworth	Ms. Maddison Shaw	Ms. Olivia Cook
Prof. Tomas Kron	A/Prof. Farshad Foroudi	Ms. Alana Rossi
A/Prof. Joerg Lehmann	Dr. John Shakeshaft	Ms. Sofee Holmes

### SECONDARY DATA ANALYSIS COMMITTEE

The Secondary Data Analysis Committee (SDAC) has continued with its mission to maximise opportunities for data from TROG trials to be used for ongoing analysis aimed at improving cancer treatment outcomes. 2020 saw a steady increase in the number of new proposals involving secondary data analysis.

These have included proposals aimed at emerging data analytics methods, such as radiomics analysis and meta-analyses across multiple trial datasets. Efforts continued to determine TROG's requirements for data archiving infrastructure, which would reduce the burden on TROG office staff in curating trial data, and will facilitate making data available to collaborating researchers.

- The assessment of seven new secondary analysis proposals.
- The development of methods for converting retrospective data into contemporary formats and confirming appropriate de-identification.
- Development of a white paper on options for a future TROG data repository.
- Partnering on a successful application to the Australian Data Research Commons (ARDC) 2020 Platforms Call, led by SDAC Committee member A/Prof. Lois Holloway, to establish the Australian

Cancer Data Network for distributed learning and for linking clinical trial data to clinical practice data. This project will see an AusCAT node installed at TROG.

 Participation in the ARDC's Health Studies National Data Assets (HeSANDA) Program consultations. This aims to ensure TROG's data infrastructure is compatible with national standards and can be included in the national data asset registry.

Focal points for 2021 will continue to make historical trial data more available, making potential collaborators more aware of TROG's data assets, seeking resources to support development of data archive infrastructure, and ensuring investigators are supported in equipping their trials to enable future secondary analyses.

Prof. Martin Ebert Chairperson

A/Prof. Richard De Abreu Lourenco

Ms. Alisha Moore

A/Prof. Lois Holloway Ms. Renee Swanson Mr. Michael Bailey Mr. Stuart Greenham Mr. Kenton Thompson Prof. Val Gebski Ms. Sofee Holmes Dr. Sweet Ping Ng

### **TROG PUBLICATIONS COMMITTEE**

Material published or presented in the name of TROG Cancer Research is an essential determinant of TROG's reputation. The TROG Publications Committee (TPC) provides peer review in the form of independent scientific review of material and timelines, helping to maintain high standards and encourage accurate, thorough and credible research reporting. We are proud to have over 359 publications attributed to TROG.

The TROG Authorship, Publication and Spokesperson guideline remains available to all TROG members via the TROG website and it is hoped that this provides guidance for investigators and authors regarding TROG sponsored research reporting.

Two TPC meetings were held in 2020 and eight reviews were completed by the TPC. A breakdown of these reviews can be found below.

	NO. OF MANUSCRIPTS REVIEWED BY TPC IN 2020	NO. OF ABSTRACTS REVIEWED BY TPC IN 2020
Category A	6	1
Category B	0	0
Category C	0	0
Not Trial Related	1	0
TOTAL	7	1

Thirteen manuscripts arising from TROG sponsored research were published in 2020, with 85% of these manuscripts acknowledging TROG appropriately! We thank all these authors for continuing to ensure TROG receives the appropriate acknowledgement. For details of these published manuscripts, please see page 41 of this report.

We are looking forward to a busy 2021 with several TROG trials nearing data maturity time-points.

A/Prof. Purnima Sundaresan Chairperson

**Prof. Trevor Leong** Radiation Oncologist and Scientific Committee Chair Prof. Val Gebski Discipline Representative – Statistics

Mr. Patrick Wheeler Secretary

## A MESSAGE FROM THE CONSUMER ADVISORY PANEL



#### John Stubbs

I know first-hand what it is like to be part of a clinical trial. I was diagnosed with Chronic Myeloid Leukaemia just over 20 years ago and I volunteered to take part in a clinical trial testing a new drug treatment.

So, like many other consumers, I joined TROG's Consumer Advisory Panel (CAP), hoping to provide support to others who are facing a cancer diagnosis and given the opportunity to participate in a clinical trial. This is my fourth year as Chair and my seventh year as a TROG Consumer representative.

As a member of the national network of Cancer Collaborative Trial Groups (CCTGs), TROG's position is somewhat different to disease-based trials groups, playing a significant role in encouraging other trial groups to consider the importance and benefits of radiation technology in cancer treatment.

Over the past few years, it has been very encouraging that patients, consumers and consumer advocates have become integral in the design and conduct of clinical trials. Consumers have the unique opportunity to contribute their knowledge and experience of having a cancer diagnosis or supporting someone during their cancer journey.

Through trial design and review of the protocols and participant information and consent forms, consumer input into clinical trials is vital to ensure that research remains patient-centred. Cancer research and clinical trials were impacted due to COVID-19, which had flow-on effects for consumer participation. For example, some trials involving immunosuppressive drugs were suspended due to associated risks, and for many patients, they were unable to travel to participate in clinical trials.

However, in Australia and New Zealand, clinical trial participation was, for the most part, able to continue in a modified way through government initiatives such as telemedicine and the streamlining of ethical and regulatory processes. Fortunately, TROG continued to prioritise the safety and well being of trial participants, clinician investigators and clinical trial research support staff.

There was also the added impact of many government funding rounds being delayed and a reduction in philanthropic funding, limiting the ability to fund cancer clinical trials. TROG'S CAP will continue to advocate for increased funding for TROG clinical trials in addition to providing feedback on how best to include consumers in TROG Research.

CAP members continue to be involved in vital research via inclusion in Board membership, participation in the Scientific Committee and participation in the TROG virtual Annual Scientific Meeting.

As health consumers and advocates, we're committed to promoting and encouraging access to cancer trials. We're making a significant contribution to TROG's mission of conducting world-class research in radiation medicine that leads the global effort to better control and cure cancer.



# We are **Precision Radiation Medicine**.

Elekta is committed to ensuring everyone in the world with cancer has access to—and benefits from—more precise, personalized radiotherapy treatments.

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# Elekta

Elekta Harmony Pro is not available in all markets

## **RESEARCH ACHIEVEMENTS**

## YEAR IN REVIEW

#### **IMPORTANT MILESTONES**

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#### BIG 3-07/TROG 07.01

Randomised Phase III Study of Radiation Doses and Fractionation in Non-Low Risk DCIS of the Breast: 5-Year Main Analysis was presented at San Antonio Breast Summit in 2020. Prof. Boon Chua (Prince of Wales Hospital, NSW) has led this landmark study.



#### **TROG 15.01 SPARK**

Trial completed follow up and was published in 2020, with Professor Paul Keall (University of Sydney, NSW) and A/Prof. Jarad Martin (Calvary Mater Newcastle, NSW) leading the study. The trial focused on the Efficacy of Kilovoltage Intrafraction Monitoring (KIM) in men with prostate cancer undergoing stereotactic prostate radiotherapy.



#### TROG 13.01/ALTG 13.001 SAFRON II

Stereotactic Ablative Fractionated Radiotherapy vs Radiosurgery for Oligometastatic Neoplasia to the Lung trial results were presented at American Society of Clinical Oncology (ASCO) in 2020 by Trial Chair A/Prof. Shankar Siva (Peter MacCallum Cancer Centre, VIC).

#### **TROG 15.03 FASTRACK**

Focal Ablative STereotactic RAdiosurgery for Cancers of the Kidney trial completed accrual in March 2020. Trial Chair: A/Prof. Shankar Siva, (Peter MacCallum Cancer Centre, VIC).

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#### TROG 16.02 Local HER-O

Local SRS/surgery for treatment of up to 5 brain metastases from HER2 positive Breast Cancer trial completed accrual in December. This trial is led by Dr. Clare Phillips (Peter MacCallum Cancer Centre, VIC).

### **NEW TRIALS OPEN/IN DEVELOPMENT**

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#### **TROG 19.06 DECREASE**

DarolutamidE + Consolidation RadiothErapy in Advanced proStatE Cancer Detected by PSMA trial was in development after funding was secured in 2020. Trial Chair: A/Prof. Siva, (Peter MacCallum Cancer Centre, VIC).

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#### TROG 20.01 CHEST RT

Chemotherapy and Immunotherapy in Extensive-Stage Small-Cell Lung Cancer with Thoracic Radiotherapy trial was endorsed and in development. Trial Chair: Dr. Eric Hau, (Westmead Hospital, NSW).

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#### **TROG 18.06 FIG**

A/Prof. Eng Siew Koh (Liverpool Hospital, NSW), Prof. Andrew Scott (Austin Hospital, VIC) and team have developed TROG 18.06 FIG (FET-PET in Glioblastoma) Trial during 2020, which was delayed due to some technical challenges, but opened the first site in December.

See more about this novel trial below.



## **TRIAL IN FOCUS!**

TROG 18.06 FIG - Prospective, multicentre trial evaluating FET-PET in Glioblastoma.

The FIG Trial (ACTRN12619001735145) will involve 10 sites nationally and up to 210 participants. The trial hypotheses are:

- The incorporation of FET-PET imaging to radiation therapy (RT) treatment planning compared to (standard) MRI-based planning alone will lead to a clinically significant change in RT target volumes for Glioblastoma (GBM) patients.
- 2. FET-PET imaging will be more accurate than routine MRI and clinical follow-up in differentiating tumour pseudoprogression from true tumour progression.
- 3. FET-PET imaging, using the parameters of dynamic uptake, tumour to background ratio, and metabolic tumour volume, will be prognostic in relation to progression-free survival and overall survival.

Glioblastoma (GBM) constitutes around 70 per cent of all gliomas and affects approximately 1,000 Australian adults annually. FET-PET imaging is not currently funded in Australia for the management of patients with GBM, either in the initial diagnosis nor when progression and/or recurrent disease is suspected. One of the key objectives of this trial will be to estimate the health economic impact and costs of incorporating FET-PET imaging into the management strategy of patients with GBM undergoing chemoradiation and in the assessment of post-treatment pseudoprogression or recurrence/progression.

Collaborators on this project include Cooperative Trials Group for Neuro-Oncology (COGNO), Australasian Radiopharmaceutical Trials Network (ARTNet) and Olivia Newton-John Cancer Research Institute (ONJCRI).

# **RESEARCH PORTFOLIO**

## TROG 2020 OVERVIEW

TROG Cancer Research continues to maintain a large and diverse portfolio of clinical trials across varied tumour groups. In 2020, there were nine trials in development, one in start-up and 29 open. A further 68 trials were either closed or completed.

	TRIAL CATEGORY				
STAGE OF TRIAL	А	В	с	D*	TOTAL
New Proposal	0	1	0	Ο	1
Development	6	2	0	1	9
Start-up	0	0	1	0	1
Open - In Follow Up	13	6	10	0	29
<b>Closed</b> (no participant activity)	16	5	2	0	23
Completed	37	7	1	0	45

#### CATEGORY KEY

- A: TROG initiated and sponsored trial
- B: International trial with TROG as Australian Sponsor
- C: Not led by TROG, but TROG collaborates with the Sponsor
- D: Consists of registries and special projects (excludes secondary analysis)

## **WORKING PARTIES**

## YEAR IN REVIEW

## TROG TUMOUR GROUP WORKING PARTIES

The TROG Cancer Research Tumour Group Working Parties play a vital role in developing the TROG clinical research portfolio via horizon scanning, concept development and working up of concepts into clinical trial protocols.

### **BREAST WORKING PARTY**

#### CHAIR | PROF. BOON CHUA

The Breast Working Party has met quarterly throughout the year to oversee the TROG breast portfolio. TROG has reached a significant milestone in the BIG 3-07 / TROG 07.01 DCIS trial, where the main results were presented at the San Antonio Summit in 2020 by Prof. Boon Chua. Practice-changing trial results will soon be published.

A total of 1,608 patients from 130 centres in 11 countries were randomised for the study. Results on the health-related quality of life at two years and international comparison of cosmetic outcomes of breast-conserving surgery and radiation therapy for women with DCIS were published in 2020 in Lancet Oncology and Radiotherapy and Oncology, respectively.

The TROG 16.04 EXPERT (ANZ 1601/BIG 16-02) study continues with the randomisation of over 375 patients to the trial by the end of 2020 from up to 35 Australian and New Zealand active centres. This collaboration with Breast International Group (BIG) and other international collaborative groups will include participation from about 50 recruiting centres worldwide.

This trial aims to improve the personalised use of radiation therapy in patients with molecularly characterised luminal A early breast cancer according to individual risks of local recurrence.

Prof. Tomas Kron presented TROG 14.04 HART results - "Timely review of electronic portal images in a multicentre clinical trial of deep inhalation breathhold in breast cancer patients" - at the Engineering and Physical Sciences in Medicine Conference in 2020. The full results are soon to be published.

Several trials have completed accrual this year, with PET LABRADOR (TROG 12.02), Local HER-O (TROG 16.02) and CORE (TROG 16.03) trials now closed.

The Breast Working Party has been exploring new trial concepts and research directions, with discussions in 2020 regarding MRI guided breast radiotherapy and radiomics in breast cancer. The Working Party has also engaged with other TROG committees including MR in RT and Particle Therapy Special Interest Groups.

### LUNG WORKING PARTY

#### CHAIRS | DR. FIONA HEGI-JOHNSON AND DR. YU YANG SOON

Exciting times for TROG 20.01 CHEST RT trial, which secured a pharmaceutical research grant in 2020 and is set to open in 2021. This trial will examine the role of immunotherapy and consolidative thoracic radiation therapy in small cell lung cancer.

TROG 17.02 OUTRUN (RCT of Osimertinib with or without stereotactic radiosurgery for EGFR mutated Non-Small Cell Lung Cancer with brain metastases) was slow to start up but will open in Singapore early in 2021. Recruitment has slowed down given PBS drug listing in Australia. The lung working party noticed challenges and delays with credentialing for SRS, which may be due to the stringent requirements of the radiation therapy quality assurance process. Sites need to perform multiple quality assurance checks, including end-to-end testing, or have passed the ACDS audit. Shankar Siva presented the TROG 13.01 SAFRON II study at ASTRO (RCT of Stereotactic ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung). Also, the TROG 11.03 P-LUNG GP (RCT of Palliative RT versus Concurrent Chemotherapy and PRT in locally advanced or metastatic NSCLC with symptoms or unsuitable for radical chemo-radiotherapy) main results were presented at ESTRO and have subsequently been accepted for publication in Practical Radiation Oncology - well done to Margot Lehman and team.

TROG lung working party members have discussed opportunities for collaboration with the Thoracic Oncology Group of Australia (TOGA) and planned for a research symposium to be held in 2021.

### **HEAD & NECK / SKIN WORKING PARTY**

#### CHAIR | A/PROF. CHARLES LIN

I am most grateful for Prof. June Corry's leadership and contribution to the working party over the years. Prof. Corry stepped down from the Chair position in late 2020 but will remain in the working party to provide guidance and mentorship.

We would like to congratulate Professor Danny Rischin and the team for the TROG 12.01 HPV publication "Validation of local p16 testing for determination of human papillomavirus status eligibility on a low-risk oropharyngeal cancer trial" in Oral Oncology.

TROG C-POST 17.11 was impacted by COVID-19 and was put on hold by Regeneron (sponsor) due to poor worldwide accrual during the pandemic, but efforts were undertaken to boost accrual. The trial team published an abstract in the Journal of Clinical Oncology - "A phase III, randomised, double-blind study of adjuvant cemiplimab versus placebo postsurgery and radiation therapy (RT) in patients with high-risk cutaneous squamous cell carcinoma".

In addition, Head and Neck Cancer International Group Consensus Guidelines for the Delivery of Postoperative Radiation Therapy in Complex Cutaneous Squamous Cell Carcinoma of the Head and Neck were published in 2020.

The Head & Neck/Skin working party have been considering opportunities for future research and would be prepared to collaborate widely at a national and international level. Secondary analyses will continue to be explored. I would like to say a big thanks to all the hardworking party members who contribute to TROG Cancer Research to ensure that high-quality research continues.

### GENITOURINARY WORKING PARTY CHAIRS | A/PROF. DAVID PRYOR AND A/PROF. SHANKAR SIVA

Whilst 2020 was a challenging year, we did see some significant milestones within the genitourinary team. A big congratulations to the TROG 08.03 RAVES trial team (led by Maria Pearse and Andrew Kneebone) with the preliminary results published in The Lancet Oncology in September and the prospectively planned ARTISTIC meta-analysis published in The Lancet in October. Congratulations also to Paul Keall, Jarad Martin and the team on their publication from the SPARK trial in the Red Journal.

TROG 15.03 FASTRACK (Focal Ablative SRS in kidney cancers), TROG 14.01 RAIDER-B (RCT of adaptive IGRT and dose escalation in bladder cancer), and TROG 16.03 CORE trial (RCT of SABR for oligorecurrent prostate cancer) have all completed accrual in 2020.

TROG 18.01 NINJA study (RCT of SABR for prostate cancer) continued to recruit well, nearing the 100 mark by the end of the year with grant submissions in the process to expand to phase 3.

Exciting developments continue with the TROG 19.06 DECREASE trial (SABR for castrate-resistant oligoprogressive prostate cancer) led by Shankar Siva, with protocol finalised and submitted for ethical approval by the end of 2020. A new proposal approved through the TROG new proposal pathway for further development - TD 20.02 CHyPPR (RCT of Conventional vs Hypofractionated Post Prostatectomy Radiotherapy) led by Stephen Chin is now in development and is seeking funding.

It's been a privilege to chair the GU working party over the past seven years and I look forward to continuing to contribute to the team under the leadership of Shankar Siva and Deputy Chair, Stephen Chin. We thank the working party members and look forward to further collaborations nationally and internationally and working with trial investigators and the TROG central office team throughout 2021.

# **TROG MEMBERSHIP**

## TROG 2020



## **TOTAL TROG MEMBERS**

DISCIPLINE	2020	FULL / LIFE MEMBER	AFFLILIATE
Radiation Oncologists	323	169	154
Radiation Therapists	522	8	514
Radiation Oncology Registrars	152	4	148
Trial Coordinators/Data Managers	189	3	186
Medical Physicists	87	7	80
Medical Oncologists	6	2	4
Interventional Oncologists	8	1	7
Statisticians	6	0	6
Consumers / Other	275	11	264
TOTAL MEMBERSHIP	1568	205	1363



## FACILITY ALLIANCE MEMBERSHIP

Thank you to our TROG Facility Alliance Members across Australia and New Zealand for your continued support and engagement with TROG Cancer Research. The Facility Alliance Membership (FAM) continues to support vital infrastructure to assist participating sites.

Members of TROG FAM receive value-added services and support from TROG, including collaborative group services, support and expertise from our RTQA team, access to essential software, training and IT infrastructure to support patient care and participation in national collaborative trials.

## PUBLICATIONS

## YEAR IN REVIEW

#### DCIS (TROG 07.01) Radiother Oncol. 2020 Jan; 142:180-5.

Olivotto I, Link E, Phillips C, Whelan T, Bryant G, Kunkler I, Westenberg A, Purohit K, Ahern V, Graham P, Akra M, McArdle O, Ludbrook J, Harvey J, Maduro J, Kirkove C, Gruber G, Martin J, Campbell I, Delaney G, Chua BH; BIG 03-07/TROG 07.01 trial investigators. International comparison of cosmetic outcomes of breast conserving surgery and radiation therapy for women with ductal carcinoma in situ of the breast. Radiother Oncol.

#### NIVORAD (TROG 16.01) Phys Med. 2020 Apr; 72:16-21.

Hardcastle N, Kron T, Cook O, Lehmann J, Mitchell P, Siva S. Credentialing of vertebral stereotactic ablative body radiotherapy in a multi-centre trial.

#### QA Project Med Dosim. 2020 Apr; 45(3):302-7.

Hardcastle N, Bignell F, Nelms B, Siva S, Kneebone A, Lao L, Cook O, Harris M, Shakeshaft J. The challenge of planning vertebral body SBRT: Optimising target volume coverage.

#### DCIS (TROG 07.01) Lancet Oncol. 2020 May; 21(5):685-698.

King MT, Link EK, Whelan TJ, Olivotto IA, Kunkler I, Westenberg AH, Gruber G, Schofield P, Chua BH; BIG 3-07/TROG 07.01 trial investigators. Quality of life after breast conserving therapy for non-low risk ductal carcinoma in situ: two-year results of a randomised controlled trial (BIG 3-07/TROG 07.01).

#### TROG J Med Imaging Radiat Oncol. 2020 Jun; 64(3):414-21.

McDowell L, Goode S, Sundaresan P. Adapting to a global pandemic through live virtual delivery of a cancer collaborative trial group conference: The TROG 2020 experience.

#### MASTERPLAN (TROG 18.04) Pract Radiat Oncol. 2020 Jun; 10(3):e136-46.

Oar A, Lee M, Le H, Hruby G, Dalfsen R, Pryor D, Lee D, Chu J, Holloway L, Briggs A, Barbour A, Chander S, Ng S, Samra J, Shakeshaft J, Goldstein D, Nguyen N, Goodman K, Chang DT, Kneebone A. Australasian Gastrointestinal Trials Group (AGITG) and Trans-Tasman Radiation Oncology Group (TROG) Guidelines for Pancreatic Stereotactic Body Radiotherapy (SBRT).

#### RADAR (TROG 03.04) Front Oncol. 2020 Jun;10:910.

Panettieri V, Rancati T, Onjukka E, Ebert MA, Joseph DJ, Denham JW, Steigler A, Millar JL. External Validation of a Predictive Model of Urethral Strictures for Prostate Patients Treated With HDR Brachytherapy Boost. Front Oncol. 2020 Jun;10:910.

#### SPARK (TROG 15.01) Int J Radiat Oncol Biol Phys. 2020 Jul; 107(3):530-8.

Keall P, Nguyen D, O'Brien R, Hewson E, Ball H, Poulsen P, Booth J, Greer P, Hunter P, Wilton L, Bromley R, Kipritidis J, Eade T, Kneebone A, Hruby G, Moodie T, Hayden A, Turner S, Arumugam S, Sidhom M, Hardcastle N, Siva S, Tai K, Gebski V, Martin J. Real-Time Image Guided Ablative Prostate Cancer Radiation Therapy: Results from the TROG 15.01 SPARK Trial.

#### C-POST (TROG 17.11) Int J Radiat Oncol Biol Phys. 2020 Jul; 107(4):641-651.

Porceddu SV, Daniels C, Yom SS, Liu H, Waldron J, Gregoire V, Moore A, Veness M, Yao M, Johansen J, Mehanna H, Rischin D, Le QT. Head and Neck Cancer International Group (HNCIG) Consensus Guidelines for the Delivery of Postoperative Radiation Therapy in Complex Cutaneous Squamous Cell Carcinoma of the Head and Neck (cSCCHN).

#### RADAR (TROG 03.04) Radioth Oncol. 2020 Sep; 150: 281-92.

Marcello M, Denham JW, Kennedy A, Haworth A, Steigler A, Greer PB, Holloway LC, Dowling JA, Jameson MG, Roach D, Joseph DJ, Gulliford SL, Dearnaley DP, Sydes MR, Hall E, Ebert MA. Relationships between rectal and perirectal doses and rectal bleeding or tenesmus in pooled voxel-wise analysis of 3 randomised phase 3 trials.

#### RAVES (TROG 08.01) Lancet Oncol. 2020 Oct; 21:1331-40.

Kneebone A, Fraser-Browne C, Duchesne G, Fisher R, Frydenberg M, Herschtal A, Williams S, Delprado W, Haworth A, Joseph D, Martin J, Matthews J, Millar J, Sidhom M, Spry N, Tang C, Turner S, Wiltshire K, Woo H, Davis I, Lim T, Pearse M. A Phase III Multi-Centre Randomised Trial comparing adjuvant versus early salvage Radiotherapy following a Radical Prostatectomy: Results of the TROG 08.03 and ANZUP "RAVES" Trial.

#### SPARK (TROG 15.01) Radiother Oncol. 2020 Oct; 151: P234-41.

Hewson E, Nguyen D, O'Brien R, Poulsen P, Booth J, Greer P, Eade T, Kneebone A, Hruby G, Moodie T, Hayden A, Turner S, Hardcastle N, Siva S, Tai K, Keall P. Is multileaf collimator tracking or gating a better intrafraction motion adaptation strategy? An analysis of the TROG 15.01 Stereotactic Prostate Ablative Radiotherapy with KIM (SPARK) trial.

#### HPV OROPHARYNX (TROG 12.01) Oral Oncol. 2020 Nov; 110:104988.

Young R, Solomon B, Corry J, Angel C, Kenny L, Porceddu S, Wratten C, Macann A, Jackson J, Herschtal A, Rischin D. Validation of local p16 testing for determination of human papilloma virus status eligibility on a low risk oropharyngeal cancer trial – A Trans-Tasman Radiation Oncology Group study.

## VIRTUAL ANNUAL SCIENTIFIC MEETING (ASM)

TROG EVENTS 2020

The TROG 2020 ASM was one with a difference. The TROG face-to-face ASM in Sydney was cancelled due to the emerging COVID 19 pandemic. Instead, we hosted our 2020 ASM as a live virtual meeting.

With very little lead time, this was managed the TROG way - by innovating, being agile and looking at ways to utilise the technology available to bring the ASM to fruition, providing attendees the opportunity to collaborate and share ideas.

Thank you to Co-Convenors Associate Professor Puma Sundaresan and Ms Jo Page, and to the Program and Organising Committee Members who pulled together to make the virtual ASM such a success. Thank you also to Encanta Event Management who were a strength behind the move to the virtual ASM.

The virtual ASM had strong engagement from both delegates and sponsors. Almost 220 people joined the virtual ASM, with viewing numbers that did not drop below 100 at any one time and an average viewing of 140. Lachlan McDowell, Susan Goode and Puma Sundaresan conducted a pre and post evaluation of the virtual ASM experience. This article has been published in JMIRO so that we can share our learning with other cancer research groups facing this issue in the future.



READ THE NEWCASTLE HERALD ARTICLE HERE

**READ THE JOURNAL PUBLICATION HERE** 



A big thank you to our speakers for adapting with us and presenting in the virtual format. All speakers gave extremely engaging, thought-provoking and inspiring presentations on their specialist topic.



**Prof. Meera Agar** Professor of Palliative Medicine, Director IMPACCT, University of Technology Sydney.



A/Prof. Cai Grau Professor, MD DMSc, Department of Oncology and Danish Centre for Particle Therapy, Aarhus University Hospital Denmark.



A/Prof. Georgia Halkett Senior Research Fellow, School of Nursing, Midwifery and Paramedicine, Curtin University, Western Australia.



A/Prof. Gerry Hanna Director of Radiation Oncology, Peter MacCallum Cancer Centre.



A/Prof. Lois Holloway Medical Physics Group Lead, Ingham Institute, Liverpool and Macarthur Cancer Therapy Centres.



Prof. Peter Hoskin Consultant Clinical Oncologist, Mount Vernon Cancer Centre, Northwood, United Kingdom, Professor of Clinical Oncology University of Manchester, United Kingdom.



Prof. Paul Keall NHMRC Senior Principal Research Fellow, University of Sydney



Prof. Sabe Sabesan Director, Department of Medical Oncology, Townsville Cancer Centre, Townsville Hospital and Health Services, Clinical Dean, College of Medicine and Dentistry, James Cook University.



### RANZCR SMART WORKSHOP

The Radiation Oncology Trainee SMART Workshop was held virtually as a full-day workshop. It was directly designed to enhance trainee knowledge and skills in statistical methods, critical appraisal of literature and research methodology.

With interactive small group sessions, guided by Radiation Oncologists and Biostatisticians, the SMART workshop was a great opportunity for trainees to "meet" with local researchers within TROG as well as international researchers. This year's SMART Workshop theme was Study Design Concepts.



### PARTICLE THERAPY WORKSHOP

The first Proton Therapy Workshop was a collaboration between TROG, RANZCR, ACPSEM and ASMIRT. We ran this as though we were holding a multi-disciplinary meeting to assess patients suitability for treatment by proton therapy and referral for treatment at the Australian Bragg Centre for Proton Therapy and Research when it opens.

Teams consisting of a radiation oncologist, medical physicist and radiation therapist from Westmead Hospital, Peter MacCallum Cancer Centre, Royal Adelaide Hospital, and Royal Brisbane and Women's Hospitals were tasked to prepare one case for a proton and photon plan comparison. Several key principles for proton therapy planning were identified.

The workshop format was a success and several more virtual workshops were conducted during 2020 to ensure centres develop proton planning skills based on a shared foundation.

# **TROGIE AWARD WINNERS**

## YEAR IN REVIEW



### OUTSTANDING CONTRIBUTION TO TROG CANCER RESEARCH

Professor June Corry was presented with this Award for her outstanding work as a mid-career researcher, with contributions in the fields of radiation oncology, and in the development of emerging technologies and techniques that has advanced oncology treatments.

Her ongoing service to TROG Cancer Research through trials and leadership has been invaluable to the progress of our organisation.

- Head & Neck/Skin working party (2014-2020)
- Publications committee (2009-2013)
- ANROTAT NPC subcommittee (2010-2013)
- Executive committee member (2005-2013)
- Mentoring of emerging clinical researchers
- 130 publications and co-authorship of a number of clinical guidelines
- Trial chair of TROG 07.04 and currently co-chairs TROG 12.01.

- Co-authored publications arising from TROG 98.02, 02.02, 05.01 and 07.04.
- Internationally recognised RTQA
   expert
- Continues to perform RTQA as a Co-PI for an IAEA study in nasopharyngeal carcinoma reviewing radiotherapy plans in low-income countries.

#### **15-YEAR SERVICE AWARD**

Joining TROG in 2006 as a Quality Assurance Radiation Therapist (QART), Alisha has contributed by providing quality solutions to ensure continual growth in radiation oncology.

Since commencing, Alisha has progressed to Senior QART and is now our Radiation Therapy Manager - overseeing the entire RTQA team. We are proud to recognise her 15 years of passion, expertise and innovation with this Service Award.



## Oncology research at GenesisCare in 2020

At GenesisCare, we challenge ourselves every day to find new and better ways to treat illness and disease and deliver better outcomes for our patients. Our participation in clinical trials allows us to collect high-quality clinical evidence to inform treatment protocols, product development and new therapies.



## GenesisCare 2020 research in numbers





## **STUDY PORTFOLIO** FULL TROG TRIAL LIST 2020

#### CATEGORY KEY

- A: TROG initiated and sponsored trial
- B: International trial with TROG as Australian Sponsor
- C: Not led by TROG, but TROG collaborates with the Sponsor
- **D:** Consists of registries and special projects (excludes
- secondary analysis)

### BREAST

**TAILOR RT (NCIC CCTG MA.39/TD 17.08)** A randomised trial of regional nodal irradiation following breast conserving surgery or mastectomy in patients with luminal A early breast cancer involving 1–3 axillary lymph nodes.

**AVATAR (TROG 20.03)** A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiotherapy) with AteZolizumab in patients with advanced Triple Negative breast Cancer.

**AZTEC (PMC 17/013/TROG 17.05)** A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiotherapy) with Atezolizumab in patients with advanced triple negative breast Cancer.

DCIS (TROG 07.01/BIG 3-07) A randomised phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma insitu (DCIS) of the breast.

**EXPERT (ANZ 1601/BIG 16-02/TROG 16.04)** A randomised phase III trial of adjuvant radiotherapy versus observation following breast-conserving surgery and endocrine therapy in patients with molecularly characterised low-risk luminal A early breast cancer.

**Local HER-O (TROG 16.02)** A phase II study of local therapy only (stereotactic radiosurgery and or surgery) for treatment of up to 5 brain metastases from HER2+ breast cancer.

**PET LABRADOR (TROG 12.02)** PET scans for locally advanced breast cancer and diagnostic MRI to determine the extent of operation and radiotherapy.

**STARS (TROG 08.06)** A Randomised comparison of anastrozole commenced before and continuing during adjuvant radiotherapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed until after radiotherapy.

**SUPREMO (Mr.C/BIG 2-04/TROG 11.01)** A phase III randomised trial to assess the role of adjuvant chest wall irradiation in 'intermediate risk' operable breast cancer following mastectomy. SUPREMO (Selective Use of Postoperative Radiotherapy after MastectOmy) BIG 2-04.

**APBI (TROG 06.02)** A Multi-centre Feasibility Study of Accelerated Partial Breast Irradiation Using Three-Dimensional Conformal Radiation Therapy for Early Breast Cancer.

**HART (TROG 14.04)** Deep Inhalation Breath Hold for reduction of cardiac toxicity in patients with left-sided breast cancer undergoing radiotherapy.

MA.20 (NCIC CTG/TROG 03.05) A Phase III Study of Regional Radiation Therapy in Early Breast Cancer.

**RAPID (OCOG/TROG 10.02)** Randomised trial of accelerated partial breast irradiation.



**CMF and RT (TROG 89.02)** Simultaneous Adjuvant Radiation and CMF Chemotherapy Following Surgery for Breast Cancer.

**Cavilon Breast (TROG 04.01)** A Paired Double Blind Randomised Comparison of Cavilon Durable Barrier Cream (CDBC) to 10% Glycerine ("Sorbolene") Cream in the Prophylactic Management of Post-Mastectomy Irradiation Skin Care.

#### BRAIN & CENTRAL NERVOUS SYSTEM

**FIG (TROG 18.06)** Prospective, multi-centre trial evaluating FET-PET in Glioblastoma.

**ROAM (EORTC 1308/TROG 15.02)** Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (The ROAM trial).

Low-Grade Glioma (EORTC 22033-26033/TROG 06.01) Primary chemotherapy with Temozolomide vs. radiotherapy in patients with low-grade gliomas after stratification for genetic 1p loss: a phase III study.

**Glioblastoma/Temozolomide (26981/22981) (EORTC/TROG 01.03)** Concomitant and Adjuvant Temozolomide and Radiotherapy for Newly Diagnosed Glioblastoma Multiforme. A Randomised Phase III Study.

**Solitary Brain Metastases (TROG 98.05)** A Randomised Trial of Immediate Versus Delayed Whole Brain Irradiation Following Surgery and/or Radiosurgery for patients with one or two brain metastases.

**QUARTZ (MRC LU24/TROG 07.02)** A Phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including Dexamethasone) is as effective as optimal supportive care (including Dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer.

**GBM in Elderly Patients (NCIC CTG CE.6/TROG 08.02)** A Randomised Phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients.





#### GASTROINTESTINAL

**SIROCCO (TD 19.02)** Sir-spheres implanted with and without Occlusafe balloon micro catheter.

MASTERPLAN (CTC 0245/AGITG AG0118PS/Trog 18.04) A randomised phase II study of MFOLFIRINOX And STEreotactic Radiotherapy (SBRT) for Pancreatic Cancer with High Risk and Locally Advanced disease.

**TOPGEAR (AGITG AG0407GR/TROG 08.08)** A randomised phase II/III trial of preoperative chemo-radiotherapy versus preoperative chemotherapy for resectable gastric cancer.

**OESOPHAGUS (TROG 03.01)** A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients treated with radiotherapy versus chemo-radiotherapy.

**PROARCT (TROG 09.01)** A phase II trial of integrated preoperative radiotherapy and chemotherapy with oxaliplatin 5-FU and folinic acid in patients with locally advanced rectal cancer.

**TROG 03.02** A Feasibility Study to Evaluate Adjuvant chemoradiotherapy for Gastric Cancer.

Accelerated Radiotherapy Oesophagus (TROG 96.03) Concomitant Accelerated Radiotherapy Boost for Good Prognosis Oesophageal Patients.

**Anal Canal (TROG 99.02)** A Prospective Single-Arm Non-Randomised Study of Concurrent Radiation and Chemotherapy For the Organ Conserving Treatment of Early Anal Canal Cancer.

**DECO (AG0307OS /TROG 08.07)** A Randomised Phase II Trial to evaluate the response of Weekly Docetaxel (Taxotere) Chemoradiotherapy +/- Cetuximab (Erbitux) for Localised Resectable Cancer of the Oesophagus.

**Oesophageal (Synchronous RT and CT/TROG 89.04)** Synchronous Radiotherapy and Chemotherapy in Oesophageal Cancer.

**TROG 98.06** Concurrent Radiotherapy and Chemotherapy for Oesophageal Cancer Patients.

**TROG 96.02** Standard Radio-Chemotherapy for Oesophageal Cancer Patients.

**Oesophagus (Localised Resectable) (TROG 94.01/AGITG IG9401)** A randomised Phase III Clinical Trial comparing surgery alone with concurrent preoperative Chemotherapy and Radiation followed by surgery for Localised Resectable Carcinoma of the Oesophagus.

**Rectal (Phase II) (TROG 98.01)** A Phase II Trial Of Preoperative Radiotherapy With Protracted Infusion 5-Fluorouracil For Resectable Adenocarcinoma Of Rectum.

**Rectal (Phase III) (TROG 01.04)** A Randomised Trial of Preoperative Radiotherapy for Stage T3 Adenocarcinoma of the Rectum.

**Rectal Cancer (TROG 95.01)** A Randomised Trial Comparing Adjuvant Protracted Venous Infusion and Bolus 5FU/Leucovorin with Either Early or Late Radiotherapy in Rectal Cancer.

TROG 89.03 Upper Aero-Digestive Track (Accelerated RT).



#### GENITOURINARY

**CHyPPR (TROG 20.02)** A phase III randomised controlled trial of Conventional vs Hypofractionated Post Prostatectomy Radiotherapy cancer.

PACE-C (ICR-CTSU/2015/10053/TD 20.05) Prostate Advances in Comparative Evidence | PACE-C: International randomised study of prostatectomy vs stereotactic body radiotherapy (SBRT) and conventional radiotherapy vs SBRT for organ-confined prostate cancer.

**DECREASE (TD 19.06)** DarolutamidE + Consolidation Radiotherapy in Advanced proStatE cancer detected by PSMA.

**ENZARAD** (ANZUP 1303/TROG 14.01) Randomised phase III trial of radiation plus androgen deprivation therapy with or without enzalutamide for high risk, clinically localised, prostate cancer.

**FASTRACK II (TROG 15.03/ANZUP 16.001)** Focal Ablative STereotactic RAdiosurgery for Cancers of the Kidney - a Phase II Clinical Trial.

**NINJA (TROG 18.01)** Novel Integration of New prostate radiation schedules with adJuvant Androgen deprivation.

**RAIDER (ICR-CTSU/2014/10049/TROG 14.02)** A randomised phase II trial of adaptive image-guided standard or dose-escalated radiotherapy in the treatment of transitional cell carcinoma of the bladder.

**RAVES (TROG 08.03)** A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy.

**TROG 02.03** Randomised phase III trial of radical chemo/radiotherapy vs radiotherapy alone in the definitive management of localised muscle-invasive TCC of the urinary bladder.

**BOLART (TROG 10.01)** A multi-centre feasibility study of online adaptive image-guided radiotherapy for muscle-invasive bladder cancer.

**PROFIT (OCOG/TROG 08.01)** A randomised trial of shorter radiation fractionation schedule for the treatment of localised prostate cancer (Prostate Fractionated Irradiation Trial).

**RADAR (TROG 03.04)** A Randomised Trial Investigating the Effect on Biochemical (PSA) Control and Survival of Different Durations of Adjuvant Androgen Deprivation in Association With Definitive Radiation Treatment for Localised Carcinoma of the Prostate.

**SPARK (USYD/TROG 15.01)** Stereotactic Prostate Adaptive Radiotherapy utilising KIM (Kilovoltage Intrafraction Monitoring) SPARK.

**TROG 97.01** A Phase II Study of Trans-Urethral Resection Followed by Synchronous Chemo-Radiation in the Definitive Management of Localised Invasive TCC of the Urinary Bladder.

**TROG 99.06** Phase I/II Study of Trans-Urethral Resection Followed by Modified Synchronous Chemo-Radiation in the Definitive Management of Localised Invasive TCC of the Urinary Bladder.





**TROG 96.01** A Randomised Trial Investigating the Effectiveness of Different Durations of Maximal Androgen Deprivation Prior to and During Definitive Radiation Therapy for Locally Advanced Carcinoma of the Prostate.

**TROG 98.03** Randomised Trial to Compare the Rates of Disease-Free Survival in Margine-Positive Patients After Radical Prostatectomy With or Without Adjuvant Post-Operative Radiotherapy.

**TOAD (TROG 03.06/VCOG PR 01-03)** A Collaborative Randomised Phase III Trial: The Timing of Intervention with Androgen Deprivation in Prostate Cancer Patients with a Rising PSA.

#### **GYNAECOLOGICAL**

**PORTEC-3 (CKTO 2006-04/TROG 08.04)** Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma.

**Cervical (FIGO Stage and Tumour Volume) (TROG 04.02)** Prospective Study to Determine the Relationships Between Survival and FIGO Stage, Tumour Volume and Corpus Invasion in Cervical Cancer.

### HEAD & NECK / SKIN

**I-MAT (MASC 03.18/TROG 20.M)** A randomised, placebo-controlled, Phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma.

TD 18.03 Atezolizumab in low risk HPV OPSCC.

**C-POST (R2810-ONC-1788/TROG 17.11)** A randomised, placebocontrolled, double-blind study of adjuvant Cemiplimab versus placebo after surgery and radiation therapy in patients with high risk cutaneous squamous cell carcinoma.

**EORTC-1219 ROG-HNCG/TROG 14.03** A blind randomised multi-centre study of accelerated fractionated chemo-radiotherapy with or without the hypoxic cell radiosensitizer nimorazole (Nimoral), using a 15-gene signature for hypoxia in the treatment of squamous cell carcinoma of the head and neck.

**HPV OROPHARYNX (TROG 12.01)** A randomised trial of weekly cetuximab and radiation versus weekly cisplatin and radiation in good prognosis locoregionally advanced HPV-associated oropharyngeal squamous cell carcinoma.

**MP3 (TROG 09.03)** A phase II efficacy study of chemo-radiotherapy in PET stage II and III Merkel cell carcinoma of the skin.







**RTN2 (MASC 01.09/TROG 08.09)** A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck.

**WBRT (MASC 01.07/TROG 08.05)** 'Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma-A randomised phase III trial.

**CETUXIMAB (TROG 07.04)** A Phase I/II trial of Cetuximab, Carboplatin and Radiotherapy for patients with locally advanced Head and Neck Squamous Cell Carcinoma.

**EAT (UON/TROG 12.03)** Eating As Treatment (EAT): An RCT of psychological training for dieticians to reduce malnutrition and depression in head and neck cancer patients undergoing radiotherapy.

**POST (TROG 05.01)** Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck.

**RadioHUM (TROG 07.03)** Radiotherapy with humidification in head and neck cancer. A randomised phase III trial of the Trans Tasman Radiation Oncology Group.

**ANZMTG 1-02/TROG 02.01** A Randomised Clinical Trial of Surgery Versus Surgery Plus Adjuvant Radiotherapy for Regional Control in Patients With Completely Resected Nodal Metastatic Melanoma. When Used as an Adjuvant to Radiation Therapy in Patients With Head & Neck Squamous Cell Carcinoma.

**EORTC 22996-24002/TROG 01.01** A Phase III Double-Blind, Randomised, Placebo-Controlled Study of Erythropoietin. When Used as an Adjuvant to Radiation Therapy in Patients With Head & Neck Squamous Cell Carcinoma.

**TROG 91.01** A Phase III Prospective Randomised Clinical Trial of Accelerated Radiotherapy (ART) for Stage III and IV Squamous Carcinoma of the Upper Aerodigestive Tract.

**TROG 98.02/EFC3344** Randomised Phase II Study of Two Different Strategies for Chemoradiotherapy in Advanced Squamous Cell Carcinoma of the Head and Neck. When Used as an Adjuvant to Radiation Therapy in Patients With Head & Neck Squamous Cell Carcinoma.

**HEADSTART (CPRR04-EFC4690/TROG 02.02)** Phase III Randomised Trial of Concomitant Radiation, Cisplatin, and Tirapazamine (SR259075) Versus Concomitant Radiation and Cisplatin in Patients With Advanced Head and Neck Cancer When Used as an Adjuvant to Radiation Therapy in Patients With Head & Neck Squamous Cell Carcinoma.

**Melanoma (TROG 96.06)** A Phase II Study of Radiation Therapy Following Nodal Surgery in Malignant Melanoma.

**Merkel Cell (TROG 96.07)** A Phase II Study of Synchronous Carboplatin/ Etoposide And Radiation In Merkel Cell Carcinoma Of The Skin.



#### LUNG

**CHEST RT (TROG 20.01)** Chemotherapy and Immunotherapy in Extensive Stage Small cell lung cancer with Thoracic Radiotherapy.

**OUTRUN (TROG 17.02)** Randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated NSCLC with brain metastases.

**NIVORAD (ALTG 14/002/CTC0135/TROG 16.01)** Randomised phase 2 trial of nivolumab and radiotherapy versus nivolumab alone in advanced non-small-cell lung cancer progressing after first line chemotherapy.

**SAFRON II (TROG 13.01/ALTG 13.001)** Stereotactic ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised phase II trial.

**PLUNG GP (TROG 11.03/ALTG)** A randomised phase III trial of high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT) in patients with good performance status, locally advanced/small volume metastatic NSCLC not suitable for radical chemo-radiotherapy.

**CHISEL (TROG 09.02)** A randomised phase III trial of highly conformal hypofractionated image-guided ("Stereotactic") radiotherapy (HypoRT) versus conventionally fractionated radiotherapy (ConRT) for inoperable early stage I non-small-cell lung cancer.

**TROG 03.07** A Randomised Phase II Study of Two Regimens of Palliative Chemoradiation Therapy in the Management of Locally Advanced Non Small Cell Lung Cancer.

**TROG 99.05** Tumour Volume as an Independent Prognosis Factor in Patients with Non-Small Cell Lung Cancer: A Protocol for a Progressive Database.



#### LYMPHOMA

**FOLSTART (TD 19.01)** A multi-centre randomised controlled trial of investigator's choice systemic therapy compared with the same systemic therapy plus low dose involved-field radiation therapy in stage IIIA low-grade follicular lymphoma.

**Follicular Lymphoma (TROG 99.03)** A Randomised Multicentre Trial Of Involved Field Radiotherapy Versus Involved Field Radiotherapy Plus Chemotherapy In Combination With Rituximab (Mabthera®) For Stage I – II Low-Grade Follicular Lymphoma.

**MALT Lymphoma (TROG 05.02)** A prospective single-arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric marginal zone lymphoma.

**ALLG HDNLHL04/TROG 03.03** An ALLG/TROG Prospective Multicentre Study of Involved-Field Radiotherapy with Transplantation for Patients with Hodgkin's Disease and non-Hodgkin's Lymphoma.

**PCNSL (TROG 01.02)** A Phase II Study of Idarubicin-Based Combined Modality Therapy in Primary Central Nervous System Lymphoma.

**Osteolymphoma (OL) (TROG 99.04/ALLG LY02)** A Prospective, Non-Randomised Study of Chemotherapy and Radiotherapy for Osteolymphoma.

**Hodgkins Disease IFRT (HD3) (ANZLG HD3/TROG 99.01)** A Prospective Study of Limited Chemotherapy and Involved Field Radiotherapy for Patients With Clinical Stage I-II Hodgkin's Disease.

**PCNSL (TROG 92.01)** A Phase II Study of Intravenous Methotrexate and Cranial Irradiation in the Treatment of Primary Central Nervous System Lymphoma (PCNSL).

#### MULTIPLE

**Particle Therapy Registry (TD 18.07)** The Australian Particle Therapy Evidence Generating Network for Rare and Difficult to treat cancers.

**NEURONE (TD 17.04)** Intracranial stereotactic radiosurgery with or without memantine.

**SEAFARER** RTQA: Sensitivity assessment system to improve quality in Radiation Oncology treatment.

VESPA RTQA: Virtual EPID Standard Phantom Audit.

**LARK (USYD/TROG 17.03)** Liver Ablative Radiotherapy utilising Kilovoltage intrafraction monitoring (KIM).

**CORE (ICR-CTSU/2015/10052/TROG 16.03)** A randomised trial of Conventional care versus Radioablation (stereotactic body radiotherapy) for Extracranial oligometastases.

**ANROTAT (TROG 11.A)** The Assessment of New Radiation Oncology Technologies and Treatment.

ARORP (TROG 11.B) ANROTAT Radiation Oncology Register Pilot.





### SYMPTOM MANAGEMENT

**BONEMETS (NCIC CTG SC.20/TROG 03.08)** A phase III international randomised trial of single versus multiple fractions for re-irradiation of painful bone metastases.

**Superdex/Spinal Cord Compression (TROG 01.05)** A Pilot Randomised Controlled Trial of Dexamethasone 96mg Versus 16mg Per Day for Malignant Spinal Cord Compression Treated by Radiotherapy - TROG SuperDex Pilot.

**Liver Metastases (TROG 98.04)** Phase II Study Examining the Efficacy of Short Fractionation Radiotherapy for the Palliation of Liver Metastases.

**Neuropathic Bone (TROG 96.05)** A Prospective Randomised Trial of Single Fraction Verses Fractionated Radiotherapy of Neuropathic Pain Due to Bone Metastases.

Liver Metastases (Glucocorticoid Steroids) (TROG 96.04) Phase III Comparison of Radiotherapy with Glucocorticoid Steroid Support for the Palliation of Liver Metastases.the Palliation of Liver Metastases.

**Proctitis (Rectal Sucralfate) (TROG 95.02)** A Phase III Double-Blind Randomised Trial of Rectal Sucralfate Suspension in the Treatment of Radiation Proctitis.





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